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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,546	01/17/2001	Lynn E. Spitler	204372000901	8827

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MORRISON & FOERSTER LLP  
3811 VALLEY CENTRE DRIVE  
SUITE 500  
SAN DIEGO, CA 92130-2332

EXAMINER
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UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/31/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/764,546**

Applicant(s)  
**Spitler et al**

Examiner  
**Ungar**

Art Unit  
**1642**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56 and 58-60 is/are pending in the application.
- 4a) Of the above, claim(s) 58 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. The Election filed April 23, 2002 (Paper No. 8) in response to the Office Action of January 11, 2002 (Paper No. 6) is acknowledged and has been entered. Claims 56 and 58-60 are pending in the application and claims 56 as drawn to myelosuppression and peripheral neuropathy as well as claims 58 and 60 are have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions Claim 56 as drawn to mucositis and claim 59 are pending in the application and are currently under prosecution.
2. Applicant's election with traverse of Group V (with respect to Groups III and VII), claim 56 in Paper No 8 is acknowledged. The traversal is on the ground(s) that the inventions have a unified nature since all three conditions are actually side effects of treatment with anti-neoplastic agents and since all of these indications have a common origin as side effects, they could be examined in the same application. It appears that Applicant is arguing that the inventions have not been shown to be distinct and independent and that the examination of all groups would not impose a serious burden on the examiner. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in Paper No.6. As to the question of burden of search, the literature search particularly relevant in this art is not coextensive. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

***Specification***

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3. It is noted that the Declaration claims priority to US Application No. 60/060,717. The specification on page 1 should be amended to indicate the claim to priority to the parent application .

Appropriate correction is required.

4. The Brief Description of the Drawings is objected to because there are numerous instances wherein the Brief Description describes a figure, for example, Figure 4 discloses Figures 4A and 4B. However the Brief Description of Figure 4 does not describe Figures 4A and 4B. Examiner has made an effort to identify these informalities but applicant must carefully review the Brief Description to identify and indicate where these informalities occur.

Appropriate correction is required.

5. The use of the trademarks such as Taxol disclosed on page 5, line 10 of the specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Each letter of the trademarks must be capitalized. See MPEP 608.01(V) and Appendix I.

Further, Examiner has made an effort to identify these informalities but applicant must carefully review the specification to identify and indicate where these informalities may be found.

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Appropriate correction is required.

***Claim Objections***

6. Claim 56 is objected to because it is drawn to non-elected limitations.

***Claim Rejections***

***Claim Rejections - 35 USC § 112***

7. Claims 56 and 59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because claim 56 recites the abbreviation MTP-PE as the soles means of identifying the claimed reagent. The use of laboratory designations only to identify a particular reagent renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct reagents. Amendment of the claims to include the complete name of the reagent followed by the abbreviation in parenthesis will obviate this rejection of the claims.

8. Claim 59 is rejected under 35 USC 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 56 and 59 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kleinerman et al (Cancer Immunol. Immunother, 1992, 34:211-220) or Kleinerman et al (Cancer Research, 1989, 49:4665-4670).

The claims are drawn to a method to ameliorate a side effect, mucositis, of antineoplasia treatment in a subject, which subject has been treated with an anti-neoplasia agent which comprises administering to said subject a pharmaceutical composition comprising MTP-PE encapsulated in multilamellar liposomes.

Kleinerman et al, 1989 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes (abstract and p. 4665, col 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (p. 4665, col 2).

Kleinerman et al, 1992 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes (abstract and p. 212, paragraph bridging cols 1 and 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (abstract).

The method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes to the same population, that is subjects that had been treated with an anti-neoplasia agent, thus the claimed method is

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anticipated because the method will inherently lead to the amelioration of mucositis. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

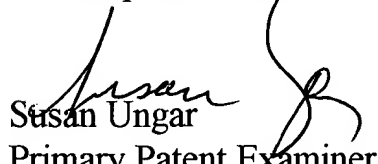
11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar

Primary Patent Examiner

May 24, 2002